

SEP 15 2009

510k Summary of Safety & Effectiveness

K092134
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This summary of 510k Safety and Effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Date of Submission: (updated 8/04/09)

Submitter/Mfg: StatRad, LLC

Company Contact: Joe Moock, CEO

Preparer/510k Contact: Linda J. Moore, Regulatory Consultant, 408-504-0565 lindajm@aol.com

Device Name: Picture Archiving & Communications System (PACS)

Common/usual name: Medical Imaging Processing/Teleradiology System

Proprietary Name: StatPacs™

Predicate device(s): Virtual Radiologic Corporation vRad PACS K090649
11995 Singletree Lane
Minneapolis, MN 55344

Mercury Computer Systems Inc. VISAGE PACS/CS
199 Riverneck Rd. K062490
Chelmsford, MA 01824-2820

VISAGE IMAGING, INC VISAGE PACS/CS
1815 ASTON AVENUE, SUITE 107 K082269
CARLSBAD, CALIFORNIA, 92008

Description/Intended use:

The StatPacs™ is a software based PACS product, intended to be used by radiologists, technologists and clinicians, to operate on specified off the shelf hardware (OTS) that will provide teleradiology and PACS solution for hospitals/clinics and remote site use. The StatPacs™ software will transmit, receive, display, and store 2D/3D images for clinical evaluation and diagnosis.

Networked gateways, including LAN/WAN through DICOM and other industry standards allow StatPacs™ to interface to all modalities including but not limited to, CT, MRI, Ultrasound (US), CR, DR, Nuclear Medicine (NM), PET, digitized radiographic films and all administration systems. StatRad, LLC provides and installs off the shelf hardware including a hospital and central server, at client hospitals and off site facilities to ensure a safe, secured, private network for image transmission via the internet. No equipment is installed in the patient environment. Additionally, VPN's and other encryption methodology are utilized and allow rapid transmission of images. Image compression and encryption adhere to standard industry protocol. StatView™ with the Exam Manager™ application is a primary user interface for processing of medical images for primary image diagnosis. StatPacs™, is not to be used for mammography imaging.

Technical Characteristics:

This is a medical imaging software device that is used with OTS computer hardware in a picture archiving and communications system user environment. The device does not contact the patient, nor does it control any life sustaining devices. The technical characteristics are similar in design, technical requirements and intended use to predicate devices.

Substantial Equivalence Summary

The StatPacs™ is substantially equivalent in design, technical requirements, and intended use to diagnostic radiological workstations, PACS and image management systems as substantiated in the feature comparison. The predicate device comparison clearly demonstrates that StatPacs™ is substantially equivalent in all areas such as functionality, user/software features, OTS hardware components and connectivity.

Conclusions:

Based on the information provided in this premarket notification submission, StatPacs™ is substantially equivalent to predicate devices and raises no new issues of safety or effectiveness from its predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

SEP 15 2009

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

StatRad LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K092134

Trade/Device Name: StatPacs™ Picture Archiving and Communications Systems (PACS)
Software

Regulation Number: 21 CFR 892.2050

Regulation Name: Picture archiving and communications system

Regulatory Class: II

Product Code: LLZ

Dated: September 1, 2009

Received: September 2, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

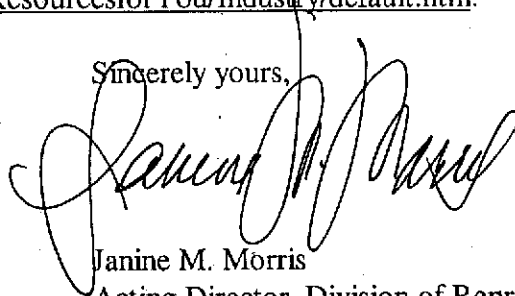
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indication for Use Statement (Section B2)

510k # K092134

Device Name:

StatPacs™ Picture Archiving and Communications Systems (PACS) Software

Indications for Use

The StatPacs™ is a software based PACS product intended to be used by radiologists, technologists and clinicians, to operate on specified off the shelf hardware that will provide a teleradiology and PACS solution for hospital and remote site use. The StatPacs™ software will transmit, receive, display, and store 2D/3D images for clinical evaluation and diagnosis by way of industry standard networked gateways including VPNs, and LAN/WAN through DICOM allowing StatPacs™ to interface to all modalities including but not limited to, CT, MRI, Ultrasound (US), CR, DR, Nuclear Medicine (NM), PET, digitized radiographic films and all administration systems. StatView™ with the Exam Manager™ application, is a primary user interface for processing of medical images for primary image diagnosis. Image compression and encryption adhere to standard industry protocol. StatPacs™, is not to be used for mammography imaging.

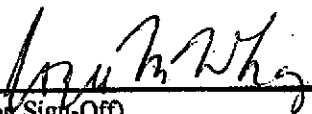
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence or CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K092134

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